

AMENDMENTS TO THE CLAIMS

1-46 (canceled).

47. (previously presented) A once a day oral pharmaceutical tablet consisting of (a) a core; (b) a primary seal coat; (c) an immediate release pioglitazone coating; and (d) optionally an aesthetic coating wherein:

the core (a) consists of:

- (i) a compressed mixture of:
 - (I) 50-98% of metformin hydrochloride;
 - (II) 0.1-40% of a binding agent;
 - (III) 0-20% of an absorption enhancer; and
 - (IV) 0-5% of a lubricant;
- (ii) optionally a secondary seal coat surrounding the compressed mixture; and
- (iii) a semipermeable membrane consisting essentially of:
 - (I) 50-99% of a polymer selected from the group consisting of ethylcellulose, cellulose esters, cellulose diesters, cellulose triesters, cellulose ethers, cellulose ester-ether, cellulose acylate, cellulose diacylate, cellulose triacylate, cellulose acetate, cellulose diacetate, cellulose triacetate, cellulose acetate propionate and cellulose acetate butyrate;
 - (II) 0-40% of a flux enhancer; and
 - (III) 0-25% of a plasticizer, said membrane having at least one passageway formed therein for release of the metformin;

the primary seal coat (b) is applied to the semipermeable membrane (iii), does not contain an active pharmaceutical ingredient and rapidly disperses or dissolves in water;

the immediate release pioglitazone coating (c) consists of:

- (i) 0.1-20% based upon the total weight of the tablet of pioglitazone hydrochloride;

- (ii) 0.1-30% based upon the total weight of the tablet of a binder;
- (iii) 0-25% based upon the total weight of the tablet of a pore former; and
- (iv) 0-20% based upon the total weight of the tablet of a surfactant;

wherein the immediate release pioglitazone coating (c) is applied to the primary seal coat (b) that is applied to the semipermeable membrane (a)(iii) of the core (a);

the tablet provides a Tmax of 8-12 hours for the metformin and a Tmax of 1-4 hours for the pioglitazone;

the tablet exhibits the following metformin dissolution profile when tested in a USP Type 2 apparatus at 75 rpms in 900 ml of simulated intestinal fluid and 37°C:

0-15% of the metformin is released after two hours;

20-40% of the metformin is released after four hours;

45-90% of metformin is released after eight hours; and

not less than 60% of the metformin is released after twelve hours;

and the tablet exhibits the following pioglitazone dissolution profile when tested in a USP apparatus Type 1 apparatus at 100 rpm in a pH 2.0 HCl-0.3M KCl buffer solution:

at least 79% of the pioglitazone is released after 20 minutes and

at least 95% of the pioglitazone is release after 30 minutes.

48. (previously presented) The tablet of claim 47 wherein the immediate release pioglitazone coating is applied to the primary seal coating using a solvent mixture of water and an organic solvent.

49. (previously presented) The tablet of claim 47 wherein the compressed mixture of the core consists of::

(I) 75-95% of metformin hydrochloride;

(II) 3-15% of a binding agent;

(III) 2-10% of an absorption enhancer; and

(IV) 0.5-1% of a lubricant.

50. (previously presented) The tablet of claim 35 wherein the polymer of the semipermeable membrane is cellulose acetate.
51. (previously presented) The tablet of claim 47 wherein the polymer of the semipermeable membrane is cellulose acetate.